

REMARKS/ARGUMENTS

Status of the Claims

Claims 1-33 are pending. Claims 28-33 are withdrawn for being drawn to non-elected subject matter. Claims 1-27 stand rejected.

Applicants have cancelled claims 28-33 without prejudice or disclaimer for being drawn to non-elected subject matter. Applicants expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the cancelled claims.

Applicants have amended claims 1, 16, 18, 19, and 21-27.

Applicants have amended claim 1 to recite that the plants or plant cells are capable of expressing a protein of interest from the DNA sequence of interest and that the process comprises providing a plant cell or a cell of a plant with at least two different vectors in one step. Support for the amendment of claim 1 can be found in the original claims and the specification particularly in the paragraph bridging pages 6-7 and on page 11 (lines 3-4).

Applicants have amended claim 16 to correct an inadvertent clerical error therein. In a particular, the comma at the end of claim 16 has been replaced with a period. The amendment is purely formal in nature and thus, does not introduce new matter.

Applicants have amended claim 18 to delete the recitation, "and/or recombination products thereof with the exception of recombination products containing said DNA sequence of interest". Applicant have also amended claim 19, which depends from claim 18, to delete certain recitations therein for consistency with the amendment of claim 18.

Applicants have amended dependent claims 21, 22, and 25 to replace "function" with --protein-- for consistency with the amendment of claim 1. Applicants have also amended

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dependent claim 23 to recite "said plant cell or cell of a plant" for consistency with the amendment of claim 1.

Applicants have amended claim 24 in response to a rejection of this claim for indefiniteness under 35 U.S.C. § 112, second paragraph, as discussed below.

Applicant have amended claims 25 and 26 to delete the parentheses therein in response to rejections of these claims for indefiniteness under 35 U.S.C. § 112, second paragraph, as discussed below.

Applicants have further amended claim 26 at part (B) to replace "function" with --protein-- for consistency with the amendment of claim 1.

Applicants have claim 27 to replace "function of" with --protein encoded by-- for consistency with the amendment of claim 1.

New claim 34 has been added. Support for the new claim can be found in the original claims and the specification, particularly in the paragraph bridging pages 6-7.

Applicants expressly reserve the right to file continuing applications or take such other appropriate measures deemed necessary to protect the full scope of the subject matter that is encompassed by the original claims.

No new matter has been added by way of the amendment of the claims or by the addition of the new claim.

Reexamination and reconsideration of the application as amended are respectfully requested in view of the following remarks.

The Objection to Claim 16 Should Be Withdrawn

Claim 16 is objected to for ending in a comma instead of a period.

To overcome this objection, Applicants have amended claim 16 to correct this inadvertent clerical error by replacing the comma at the end of claim 16 with a period. Accordingly, this objection should be withdrawn.

The Rejections of the Claims Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn

Claims 1-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as their invention. Claims 1, 16, 18, 19, and 21-27 have been amended. New claim 34 has been added. This rejection is respectfully traversed and should not be applied to the newly submitted claim.

In the Office Action, the Examiner alleges that in claim 1, transgenic plants or plant cells cannot be stably transformed on a chromosome but provides no further explanation

Applicants respectfully disagree with this position of the Examiner because one of ordinary skill in the art would not find claim 1 indefinite upon considering the entire preamble of claim 1, which reads (after the amendments made hereinabove): "[a] process of producing transgenic plants or plant cells stably transformed on a chromosome with a DNA sequence of interest, said plants or plant cells being capable of expressing a protein of interest from said DNA sequence of interest" Applicants submit that a person having ordinary skill in the art would understand what Applicants intend in their preamble by the recitation, "plants or plant cells stably transformed on a chromosome with a DNA sequence of interest", particularly that a chromosome of the plant or plant cell is transformed with the DNA sequence of interest. Accordingly, claim 1 is not indefinite for the recitation therein of "stably transformed on a chromosome" as alleged in the Office Action.

The Examiner alleges that in claim 1(a), "plant cells or plants" be amended to a plant cell. Applicants have amended claim 1 at part (a) to replace "plant cells or a plant" with --a plant cell or a cell of a plant--.

On page 2 of the Office Action, the Examiner alleges that in claim 1, a function cannot be expressed and questions whether Applicants mean a protein instead. Applicants have amended claim 1 to replace "function" with --protein--.

The Examiner alleges that it is unclear in claim 1 what "capable" refers to. Applicants have amended claim 1 to recite "said plants or plant cells being capable of expressing a protein of interest"

The Examiner alleges that in claim 1(iii), the recitation, "from at least two of said at least two different vectors " is unclear. Applicants have amended this recitation to read, "from said at least two different vectors".

In view of the amendment of claim 1 and above remarks, Applicants submit that amended claim 1 is not indefinite.

The Examiner alleges that in claim 18, it is unclear what is being screened for. Applicants have amended claim 18 to recite that the screening is for the absence of said at least two different vectors. As amended, claim 18 is not indefinite.

The Examiner alleges that in claim 21, it is unclear how the DNA sequence of interest can comprise intron-mediated cis-splicing, as splicing is a step and not a product. Applicants have amended claim 21 to recite "wherein said expression of said protein of interest from said DNA sequence of interest comprises intron-mediated cis-splicing." As amended, claim 21 is not indefinite.

The Examiner alleges that in claim 24, it is unclear whether the DNA sequence of interest contains a sequence portion of the two vectors, or the two vectors contain a sequence portion of the DNA sequence of interest. Applicants have amended claim 24 to recite "said DNA sequence of interest contains a sequence portion from each of these two vectors". As amended, claim 24 is not indefinite.

The Examiner alleges that in claim 25, it is unclear whether what is in the parentheses is intended to be a claim limitation and also indicates that this applies for claim 26. Applicants have amended claims 25-26 to delete the parentheses therein.

The Examiner alleges that the Markush grouping in claim 25 cannot be an open set and also indicates that this applies for claim 26.

Applicants do not believe that either claim 25 or 26 include Markush groups and Examiner does not provide in the Office Action a sufficient description of what the Office considers to be the Markush groups in claims 25 and 26. In a good faith attempt to address this rejection, Applicants believe that the alleged Markush groups may be found in subparts (A)(i) and (A)(ii) of claim 25 and part (A)(ii) in claim 26. For example, in amended claim 25, subpart (A)(i) recites, "a set of m primary vectors each having a primary sequence portion selected from the set $a_1, a_2, \dots, a_m \dots$." Applicants believe that the Examiner might have misunderstood the recitation therein "selected from the set a_1, a_2, \dots, a_m " to represent a Markush group, wherein " a_1, a_2, \dots, a_m " represent a listing of alternatives that is an open set. However, the recitation " a_1, a_2, \dots, a_m " is not a listing of alternatives in Markush group but rather a listing of the primary sequence portions in set of " m " primary vectors. For example, if " m " is 3, then the set of primary sequence portions is a_1, a_2 , and a_3 , or if " m " is 5, then the set of primary sequence portions is a_1, a_2, a_3, a_4 , and a_5 . Accordingly, claims 25 and 26 are not indefinite because these claims lack Markush groups that are open sets.

The Examiner alleges that in claim 26, it is unclear how a_1b_1 differs from b_1a_1 .

Applicants respectfully disagree with this position because a person having ordinary skill in the art in view of Applicants' original specification, drawings, and claims would understand that these abbreviations in the claim 26 refer to nucleotide sequences. A person having ordinary skill the art also knows that nucleotide sequences have an orientation both on the chemical level (5' to 3') and consequently also on the functional level. Thus, it is clear for a person having ordinary skill the art that a_1b_1 and b_1a_1 differ in the order of portions a_1 and b_1 . In particular, a person having ordinary skill the art would know that in a DNA sequence of type a_1b_1 , a_1 is 5' of b_1 and that in a DNA sequence of type b_1a_1 , b_1 is 5' of a_1 and therefore, clearly understand the

structural difference between a_1b_1 and b_1a_1 as recited in claim 26. Accordingly, claim 26 is not indefinite.

The Examiner alleges that in claim 27, it is unclear what function the primary, secondary, and their combination portions have because the function is not disclosed.

Applicants have amended claim 27 by replacing "function" with --protein-- for consistency with the amendment of claim 1. As amended, claim 27 is not indefinite.

In view of the amendments and above remarks, it is submitted that the rejection of the claims under 35 U.S.C. § 112, second paragraph, should be withdrawn and not applied to the newly submitted claim.

The Rejection of the Claims for Nonstatutory Double Patenting is Improper

Claims 21 and 22 are "provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9-12, 14, 17 and 20-22 of *co-pending Application No. 10/5441135*." Office Action, Sep. 30, 2010, p. 4 (emphasis added).

Applicants believe that this rejection is improper because the Examiner has not cited a co-pending application in making this provisional rejection but has instead cited the present application (No. 10/544,135). Possibly, the Examiner made a typographical error in citing the present application in this provisional rejection.

Applicants respectfully request the Office to either withdraw this provisional rejection or to provide in the next *non-final Office Action* the application number of the co-pending application upon which this provisional rejection is based, so as to provide Applicants with a proper opportunity to respond to this provisional rejection.

The Rejection of the Claims Under 35 U.S.C. § 102(e) Should Be Withdrawn

Claims 1-27 are rejected under 35 U.S.C. § 102(e) as being anticipated by Klimyuk *et al.* (U.S. Pat. App. Pub. No. 2005/0066384). Claims 1, 16, 18, 19, and 21-27 have been amended.

New claim 34 has been added. This rejection is respectfully traversed and should not be applied to the newly submitted claim.

Applicants have amended claim 1 to recite that their claimed process involve *inter alia* providing a plant cell or a cell of a plant with at least two different vectors in one step. Applicants submit that amended claim 1 and its respective dependent claims are not anticipated by Klimyuk *et al.*, because Klimyuk *et al.* fails to disclose a process of producing a transgenic plant or plant cells, comprising providing a plant cell or a cell of a plant with at least two different vectors in one step. Klimyuk *et al.* describes two general embodiments represented by claims 1 and 2 thereof. In the embodiment of claim 1 of Klimyuk *et al.*, only one vector is used ("providing plant cells with an amplification vector ..."). In the embodiment of claim 2, two vectors are used that are referred to as "first DNA" and "second DNA". However, these DNAs are not provided to a plant in one step, but in separate steps that are even separated by a step (ii) of selecting a cell which contains a target site provided by the first DNA.

The experiment described in Example 2 of Klimyuk *et al.* is not a process of producing a transgenic plant or plant cells stably transformed on a chromosome with a DNA sequence of interest. Further, feature (ii) of claim 1 of the present application is not fulfilled. Moreover, no selection step (b) of claim 1 is carried out nor intended, since the purpose of Example 2 of Klimyuk *et al.* is merely to show that replication of a plasmid can increase the frequency of recombination with a target co-transformed non-replicating plasmid (see paragraph 137 of Klimyuk *et al.*). This is done in a transient experiment by co-bombarding two vectors in wild-type plant leaf.

In view of the amendments and above remarks, it is submitted that the rejection of the claims under 35 U.S.C. § 102(e) should be withdrawn and not applied to the newly submitted claim.

The Rejections of the Claims Under 35 U.S.C. § 102(b) Should Be Withdrawn

Claims 1-3, 5, 9-15, 18, 19, and 24-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Offringa *et al.* (U.S. Patent No. 5,501,967). Claims 1, 18, 19, and 24-27 have been amended. New claim 34 has been added. This rejection is respectfully traversed and should not be applied to the newly submitted claim.

The Examiner alleges that Offringa *et al.* anticipates Applicants' claimed invention, asserting that Offringa *et al.* teaches a site-specific homologous recombination method for producing transgenic plants stably transformed on a chromosome with two vectors introduced by two different *Agrobacterium* strains.

Applicants respectfully disagree with the allegation that Offringa *et al.* anticipates Applicants' claimed invention because Offringa *et al.* fails to disclose providing a plant cell or a cell of a plant with at least two different vectors adapted to recombine with each other by site-specific recombination. Instead, Offringa *et al.* describes site-directed integration of a DNA into a selected target locus of a genome (see claim 1 of Offringa *et al.*). Site-specific recombination and site-directed integration are different processes.

Further, site-specific recombination and homologous recombination are also different processes. The copy of page 967 from the textbook Genes V (1995; *see*, Applicants' IDS, submitted concurrently herewith) shows that it was the general understanding of the skilled person before the priority date of the present patent application that there are different types of recombination. Thus, homologous recombination and site-specific recombination have been considered different types of recombination. Consequently, homologous recombination is generically different from site-specific recombination, and homologous recombination as disclosed by Offringa *et al.*, does not anticipate site-specific recombination.

Site-specific recombination involves short stretches of homology between two DNA sequences and an enzyme that acts only on the particular pair of target sequences. Homologous recombination also involves enzymes, but these are not specific to a particular pair of target sequences. Further, stretches of homology are long. The meaning of the terms "homologous

recombination" and "site-specific recombination" as defined above in also in line with the use of these terms in the references that have been cited by the Office. Thus, homologous recombination as disclosed by Offringa *et al* does not anticipate site-specific recombination of Applicants' claimed invention.

In view of the amendments and above remarks, it is submitted that the rejection of the claims under 35 U.S.C. § 102(b) should be withdrawn and not applied to the newly submitted claim.

The Rejections of the Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-15, 18, 19, and 21-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Offringa *et al.* (U.S. Patent No. 5,501,967) as applied to claims 1-3, 5, 9-15, 18, 19, and 24-27 above and further in view of Fabijanski *et al.* (U.S. Patent No. 7,112,721). Claims 1-3, 5, 9-20, and 24-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Offringa *et al.* as applied to claims 1-3, 5, 9-15, 18, 19, and 24-27 above and further in view of Atabekov *et al.* (U.S. Patent No. 6,376,745). Claims 1, 16, 18, 19, and 21-27 have been amended. New claim 34 has been added. These rejections are respectfully traversed and should not be applied to the newly submitted claim.

The Examiner refers to the teachings of Offringa *et al.* that are discussed in the Office Action in the section concerning the rejection of the claims under 35 U.S.C. § 102(b) and summarized above by Applicants.

Concerning the rejection of the claims as being unpatentable over Offringa *et al.* in further view of Fabijanski *et al.*, the Examiner acknowledges that Offringa *et al.* does not teach a functional cytokinin autonomy gene, a site-specific recombinase or an intron. The Examiner asserts that Fabijanski *et al.* teaches a method for introducing a DNA sequence of interest into the plant genome by introducing a vector containing a DNA sequence of interest and an *Agrobacterium* oncogene to select for transformed cells, whereby the oncogene region is later excised by site-specific recombinase and the DNA sequence of interest is inserted into the plant

genome by homologous recombination and also teaches the inclusion of a plant intron to prevent expression in bacteria cells. The Examiner then concludes that it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to include the oncogene and recombinase coding sequence of Fabijanski *et al.* in one of the vectors of Offringa *et al.* for the purpose of increasing the efficiency of the screening/selecting for transformants and alleges that one skilled in the art would have been motivated to produce the claimed invention with a reasonable expectation of success.

Concerning the rejection of the claims as being unpatentable over Offringa *et al.* in further view of Atabekov *et al.*, the Examiner asserts that Offringa *et al.* further teaches a negative selection gene. The Examiner acknowledges that Offringa *et al.* does not teach an IRES element. The Examiner asserts that Atabekov *et al.* teaches gene expression under the control of IRES and advantages of using IRES for gene expression. The Examiner then concludes that it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to modify one of the two vectors of Offringa to include an IRES element for expression of a selectable marker for the purpose of selecting for plant transformants and asserts that the advantages of including an IRES element are taught by Atabekov *et al.* The Examiner further concludes that it would also have been obvious to allow transcription of the selectable marker as a result of site-specific recombination rather than from one of the vectors of Offringa *et al.* to select for transformants that have undergone site-specific recombination in the homologous recombination method of Offringa *et al.* The Examiner further asserts that the use of a positive or negative selectable marker is a matter of design choice without any surprising or unexpected results and alleges that one skilled in the art would have been motivated to produce the claimed invention with a reasonable expectation of success.

In rejecting the claims as being unpatentable over Offringa *et al.* in combination with either Fabijanski *et al.* or Atabekov *et al.*, it is apparent that the Examiner has misunderstood Applicants' claimed invention and failed to appreciate the fundamental differences between their invention and the method of Offringa *et al.* as explained below.

The present invention relates to a process of producing transgenic plants or plants cells stably transformed on a chromosome with a DNA sequence of interest. Offringa *et al.* relates to a process for site-directed integration of DNA sequences into a selected target locus of a nuclear plant genome via homologous recombination (see claim 1, abstract). The present invention, however, neither relates to site-directed integration of DNA sequences into the genome of plants, nor to homologous recombination. Thus, Offringa *et al.* is remote from the present invention.

In the course of the development of their method, Offringa *et al.* made an experiment for testing the possibility of homologous recombination between two T-DNAs in a plant cell by transforming tobacco protoplasts with two T-DNAs (Example 3 of Offringa *et al.*). The method of Offringa *et al.* that is based on homologous recombination suffers from the disadvantage that the two vectors used require long homologous sequences for enabling homologous recombination. In the examples of Offringa *et al.*, these homologous sequences comprise substantial portions of a gene. Thus, both vectors share substantial sequence portions. These long homologous sequence portions have to be cloned in both vectors. Further, these long homologous sequences are difficult to use for changing or introducing genetic elements, which makes the system very inflexible and cumbersome. Moreover, the long homologous sequence is present in the reaction product of the homologous recombination reaction, which means that different elements to be combined by homologous recombination cannot be closer to each other in the reaction product than the length of the homologous sequence used. Again, this severely limits the usability and flexibility of the system of Example 3 of Offringa *et al.* Accordingly, assembly of elements A and B to a sequence AB (as depicted in Fig. 1 of the present patent application) without large intervening sequences derived from the long homologous sequences in between elements A and B in AB is not considered by Offringa *et al.*

Claim 1 of the present application as amended herein differs from Offringa *et al.*, in that Offringa *et al.* does not disclose a process of producing transgenic plants or plant cells stably transformed on a chromosome with a DNA sequence of interest and capable of expressing a protein of interest from said DNA sequence of interest, said process comprising providing a plant cell or a cell of a plant with at least two different vectors in one step, whereby said at least two

different vectors are adapted to recombine with each other by site-specific recombination in said plant cells for producing a non-replicating recombination product containing said DNA sequence of interest. The effect of this difference is that a highly flexible and versatile system for combining nucleic acid portions from two different vectors is obtained. Only the short sequence derived from the site-specific recombination is present in the reaction product and different elements can be combined in close proximity in the DNA sequence of interest as shown schematically in the figures of the present patent application. Further, the process of the invention is highly efficient and controllable, since the site-specific recombinase can be provided to the plant cell or cell of a plant, whereby the process is not dependent on the presence of an enzyme of the host cell that can catalyze homologous recombination.

Applicants' claimed invention is not rendered obvious by the combination of Offringa *et al.* with Fabijanski *et al.* or Atabekov *et al.* for the following reasons. Offringa *et al.* does not teach or even suggest a method involving site-specific recombination. In fact, the use of site-specific recombination would even be contrary to Offringa *et al.*, since Offringa *et al.* relates to site-specific integration into a desired target locus of the genome via homologous recombination. With homologous recombination, any target locus the sequence of which is known can be targeted by using suitable homologous sequences on the vector (see definition of box 3 in claim 1 of Offringa *et al.*). This is not possible by site-specific recombination, since the genomes typically do not contain site-specific recombination sites of a given site-specific recombinase at a desired locus. Therefore, a person having ordinary skill in the art would not be motivated by the teachings of Offringa *et al.* to produce Applicants claimed invention in view of but instead would be deterred from site-specific recombination in the context of the teaching of Offringa *et al.* which relates to homologous recombination. A person having ordinary skill in the art that is interested in site-targeted integration system and considering Offringa *et al.* has no reason or motivation to change the teaching of Offringa *et al.* such that site-targeted integration is severely limited or deteriorated. Neither Fabijanski *et al.* nor Atabekov *et al.* overcomes the deficiencies in Offringa *et al.* that are set forth above, nor do either of these references provide the motivation to modify the method of Offringa *et al.*, which is drawn to site-specific integration into a desired

target locus of the genome via homologous recombination, to produce Applicants' claimed process of producing transgenic plants or plant cells stably transformed on a chromosome with a DNA sequence of interest and capable of expressing a protein of interest from said DNA sequence of interest, said process comprising providing a plant cell or a cell of a plant with at least two different vectors in one step, whereby said at least two different vectors are adapted to recombine with each other by site-specific recombination in said plant cells for producing a non-replicating recombination product containing said DNA sequence of interest.

In summary, one of skill in the art would not find that the subject matter encompassed by the amended claims is obvious in view of either the combination of Offringa *et al.* and Fabijanski *et al.* or the combination of Offringa *et al.* and Atabekov *et al.* Neither combination provides all of the elements of the amended claims. Therefore, the Examiner has failed to raise a *prima facie* case of obviousness under 35 U.S.C. § 103(a) against the amended claims based on either the combination of Offringa *et al.* and Fabijanski *et al.* or the combination of Offringa *et al.* and Atabekov *et al.*

In view of the amendments and above remarks, it is submitted that the rejections of the claims under 35 U.S.C. § 103(a) should be withdrawn and not applied to the newly submitted claim.

Status of the Claims of Co-Pending Application No. 10/545,665

The pending claims of co-pending Application No. 10/545,665 (U.S. National Stage of PCT/EP2004/000891, filed January 30, 2004) are drawn to a process a process of endowing a plant or plant cells with a trait of interest by expressing an RNA sequence of interest. The process comprises providing by co-transformation plant cells or cells of the plant with a first vector and a second vector and selecting cells endowed with said trait of interest, wherein the first vector contains a first nucleotide sequence with a first segment coding, in 5' to 3' direction, for a 5' part of said RNA sequence of interest and a 5' part of an intron; and the second vector contains a second nucleotide sequence with a second segment coding, in 5' to 3' direction, for a 3'

part of an intron and a 3' part of said RNA sequence of interest; wherein said 5' part of an intron and said 3' part of an intron form said RNA sequence of interest by splicing of a primary transcript containing said 5' part of said RNA sequence of interest, said 5' part of an intron, said 3' part of an intron, and said 3' part of said RNA sequence of interest, thereby forming said RNA sequence of interest as a secondary transcript. Claims 1-3, 6-14, 16-19, and 22 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Patten *et al.* (2003, U.S. Patent No. 6,531,316) in view of Coughlan (2003, U.S. Patent No. 6,566,584). Claims 1-3, 6-14, 16-19, 22, and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Patten *et al.* in view of Coughlan and Smith *et al.* (2000, *Nature* 407:319-320). Claims 1-3, 6-14, 16-19, 22, and 23 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of co-pending Application No. 10/544,135. Claims 1-3, 6-14, 16-19, and 22 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22 of co-pending Application No. 10/544,135 in view of Smith *et al.* (2000, *Nature* 407:319-320).

CONCLUSIONS

In view of the above amendments and remarks, Applicants submit that the objection to claim 16 and the rejections of the claims under 35 U.S.C. §§ 102, 103, and 112, second paragraph, are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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